

**Notice of Allowability**

Application No.

10/760,494

Applicant(s)

ZAZOPOULOS ET AL.

Examiner

Nashaat T. Nashed, Ph. D.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/30/07.
2. ☒ The allowed claim(s) is/are 28, 39 and 40.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 8/13/04 & 7/7/05
- ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- ☐ Notice of Informal Patent Application
- ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
- ☒ Examiner's Amendment/Comment
- ☒ Examiner's Statement of Reasons for Allowance
- ☐ Other \_\_\_\_\_

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is directed to the polypeptide of SEQ ID NO:31. Since the prior art does not teach or suggest the polypeptide of SEQ ID NO:31, the claims are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTWTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen K. Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nashed/  
Nashaat T. Nashed, Ph. D.  
Primary Examiner  
Art Unit 1656

Applicant's election with traverse of the polypeptide of SEQ ID NO: 31 in the reply filed on October 30, 2007 is acknowledged. The traversal is on the ground(s) that the various catalytic domains comprised in SEQ ID NO: 31 and SEQ ID NO: 31 overlap. This is not found persuasive because the relationship between the catalytic domains found in SEQ ID NO: 31 and SEQ ID NO: 31 is that of a combination/subcombination. The specific combinations of SEQ ID NO: 31 has a specific function disclosed for the biosynthesis of polyene in the specification, whereas the subcombinations, the independent catalytic domains having different enzymatic activities do not require the specific subcombinations for their function and are functional in different combination. The catalytic domains of polyketide synthases are functional in any other polyketide synthases.

The requirement is still deemed proper and is therefore made FINAL.

The application is amended as requested in the communications filed October 30 and November 30, 2007. Accordingly, claims 1-27, 29-38, and 41-45 are canceled, claim 28 is amended, and new claims 39-45 are entered.

Claims 28, 39, and 40 are pending.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Drew Hissong on December 4, 2007.

The application has been amended as follows:

Amend claim 39 as shown bellow:

Claim 39. An isolated polypeptide comprising an amino acid sequence having at least 95% identity to the amino acid sequence set forth in SEQ ID NO:31, and having polyene polyketide synthase activity.

Claims 28, 39, and 40 are allowed.

The following is an examiner's statement of reasons for allowance: The specification teaches the nucleic acid sequence of the gene cluster encoding the polypeptides required for the biosynthesis of *Streptomyces aizunensis*. Also, it teaches the genetic organization of the gene clusters and the various open reading frames as well as the polypeptides encoded thereby including the polypeptide of SEQ ID NO:31. In addition, it teaches the use of the gene cluster to make polyenes and their derivatives to produce compounds with antifungal and anticancer activities. The elected invention